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(H)

28/09/090 867

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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/090,867 | 06/04/98 | BAUMGARTNER | J 95-38D1 |
| | | EXAMINER | |
| | | HM12/0203 | |
| GARY E PARKER ZYMOGENETICS INC 1201 EASTLAKE AVENUE EAST SEATTLE WA 98102 | | LAZAR WESLEY, F | |
| | | ART UNIT | PAPER NUMBER |
| | | 1646 | 5 |
| | | DATE MAILED: | 02/03/99 |

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on _____
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-32 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-32 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) _____
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 13, 21, 26, 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are to a polynucleotide encoding a sequence selected from the group consisting of:

- a) residues 141-337 of SEQ ID No:2; and
- b) allelic variants of (a)

Claims are also to an expression vector and to a polypeptide comprising a segment selected from the group consisting of a) and b).

The written description sets forth SEQ ID No:1 that reveals an open reading frame encoding SEQ ID No:2 having 380 amino acids (page 10, lines 4-9). The specification discloses a DNA and protein sequence from an additional human clone (SEQ ID No:3 and 4, page 12, lines 14-16).

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However, the written description is not commensurate in scope with the claims drawn to an allelic variant of a DNA encoding the polypeptide comprising residues 141-337 of SEQ ID No:2.

Rieger et al., *Glossary of Genetics and Cytogenetics, Classical and Molecular*, 4th Ed., Springer-Verlag, Berlin, 1976) clearly defines alleles as one or two or more alternative forms of a gene occupying the same locus on a particular chromosome.... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of the sequences disclosed, the skilled artisan cannot envision the detailed structure of the encompassed allelic variant and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is a part of the invention and a reference to a potential method of isolating it. The structure itself is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins et al., US Patent 5,710,023 (A) , filed March 01, 1998, cited by applicants.

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Collins et al. teach an Interleukine 13 cytokine receptor chain . They teach polynucleotides encoding a peptide of SEQ ID No.4, whose sequence is identical to the peptide having SEQ ID No2 from the instant invention from position 1-380 (see sequence comparison attached). They teach that the mature human IL-13bc has the sequence of amino acids 26-380 of SEQ ID No.4, and they teach that the mature human receptor has an extracellular domain, a transmembrane domain, and an intracellular domain (col.4, lines 15-22). They teach, col. 4, lines 32-36, that soluble forms of IL-13bc can be produced (amino acids 1-341 or 26-341 of SEQ ID No.4). They teach suitable host cells for the expression of the IL-13bc protein (col.5, lines 46-57) . They teach methods which use the IL-13bc proteins to screen for agents which are capable of binding to IL-13bc or which interfere with the binding of IL-13 to IL-13bc. They teach that the IL-13bc may be immobilized on a carrier (col.7, lines 14-28). They teach fusion proteins wherein the specified amino acid sequence is part of a fusion protein, and preferred fusion proteins comprising an antibody fragment such as an Fc fragment (col.3, lines 4 to 9). They teach to determine whether a IL-13 bc protein has a biological activity using reporter genes (col.15, lines 1-3).The teachings of Collins meet the limitations of the claims.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW
1/29/99


LILA FEISEE
SUPERVISORY PATENT EXAMINER

09/08/867

RESULT 4
ID US-08-609-572-4 STANDARD: PRT: 380 AA.

XX

AC *****

XX

DT 01-JAN-1900

XX DE Sequence 4, Application US/08609572.

XX CC Sequence 4, Application US/08609572 → PN 5710 023

GENERAL INFORMATION:

CC APPLICANT: Collins, Mary

CC APPLICANT: Donaldson, Debra

CC APPLICANT: Fitz, Lori

CC APPLICANT: Neben, Tamlyn

CC APPLICANT: Whitters, Matthew

CC APPLICANT: Wood, Clive

CC TITLE OF INVENTION: CYTOKINE RECEPTOR CHAIN

CC NUMBER OF SEQUENCES: 9

CC CORRESPONDENCE ADDRESS:

CC ADDRESSEE: Genetics Institute, Inc.

CC STREET: 87 Cambridge Park Drive

CC CITY: Cambridge

CC STATE: MA

CC COUNTRY: USA

CC ZIP: 02140

CC COMPUTER READABLE FORM:

CC MEDIUM TYPE: Floppy disk

CC COMPUTER: IBM PC compatible

CC OPERATING SYSTEM: PC-DOS/MS-DOS

CC SOFTWARE: PatentIn Release #1.0, Version #1.25

CC CURRENT APPLICATION DATA:

CC APPLICATION NUMBER: US/08/609,572

CC FILING DATE:

CC CLASSIFICATION: 530

CC ATTORNEY/AGENT INFORMATION:

CC NAME: Brown, Scott A.

CC REGISTRATION NUMBER: 32,724

CC REFERENCE/DOCKET NUMBER: GI5268

CC TELECOMMUNICATION INFORMATION:

CC TELEPHONE: (617) 498-8224

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CC INFORMATION FOR SEQ ID NO: 4:

CC SEQUENCE CHARACTERISTICS:

CC LENGTH: 380 amino acids

CC TYPE: amino acid

CC TOPOLOGY: linear

CC MOLECULE TYPE: protein

SQ SEQUENCE 380 AA; 44176 MW; 816181 CN;

Query Match 100.0% Score 2958; DB 67; Length 380;
Best Local Similarity 100.0% Pred. No. 5.09e-274;
Matches 380; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Db 1 MAFVCLAIGCLYTFLISTTFGCTSSSDTEIKVNPPQDFEIVDPGYLGYLQLWQPPLSLD 60

Qy 1 MAFVCLAIGCLYTFLISTTFGCTSSSDTEIKVNPPQDFEIVDPGYLGYLQLWQPPLSLD 60

Db 61 HFKECTVEYELKYRNIGSETWKIITKNLHYKGDFDLNKGIEAKIHTLLPWQCTNGSEVQ 120

Qy 61 HFKECTVEYELKYRNIGSETWKIITKNLHYKGDFDLNKGIEAKIHTLLPWQCTNGSEVQ 120

Db 121 SSWAETTYWISPQGIPETKVQDMDCVYYNWQYLLCSWKPGIGVLLDTNYNLFYEGLDH 180

Qy 121 SSWAETTYWISPQGIPETKVQDMDCVYYNWQYLLCSWKPGIGVLLDTNYNLFYEGLDH 180

Db 181 ALQCVDYIKADGQNIGCRFPYLEASDYKDFYICVNGSENKPIRSSYFTFQLQNLIVKPLP 240

Qy 181 ALQCVDYIKADGQNIGCRFPYLEASDYKDFYICVNGSENKPIRSSYFTFQLQNLIVKPLP 240

Db 241 PVYLTFTRESSCEIKLKWSIPLGPIPACRFDYIEIREDDTTLVTATVENETTLKTTNE 300

Qy 241 PVYLTFTRESSCEIKLKWSIPLGPIPACRFDYIEIREDDTTLVTATVENETTLKTTNE 300

Db 301 TRQLCFVVRSKVNIYCSDDGIWSEWSDKOCWEGEDLSKTTLLRFWLPPGFILILVLIFVTG 360

Qy 301 TRQLCFVVRSKVNIYCSDDGIWSEWSDKOCWEGEDLSKTTLLRFWLPPGFILILVLIFVTG 360

Db 361 LLLRKPNTPKMIPEFFCDT 380

Qy 361 LLLRKPNTPKMIPEFFCDT 380